

PATENT

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MARKED-UP SUBSTITUTE SPECIFICATION UNDER 37 C.F.R. §1.125

Sir:

The following is a marked up version of the substitute specification filed concurrently herewith. This marked-up version shows differences between the substitute specification and the immediately previously filed version with cross-pout showing deletions and underlining showing insertion, as required in 37 C.F.R. §1.125(c).

CROSS-REFERENCE TO RELATED APPLICATIONS

~~This application claims the benefit of United States provisional application No. 60/186,200 entitled "Multiple Cannula Image Guided Tool for Image Guided Procedures," filed March 1, 2000.~~

This application is a divisional of United States Patent Serial No. 09/795,126, filed on March 1, 2001, which claims the benefit of U.S. Provisional Serial No. 60/186,200, filed March 1, 2000. The disclosures of the above applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of Invention

The present invention is directed generally to image-guided medical procedures, and more particularly, to instrumentation for the optimal placement of multiple surgical ~~implants~~ implements using image-based surgical guided navigation systems.

2. Description of the Related Art

Many surgical procedures ~~require~~ include a surgeon to ~~place~~ placing multiple ~~implants~~ implements within a patient's body. Some of these procedures ~~require~~ dictate ~~implement~~ placement in a specific geometry to maximize the effectiveness of the treatment. Certain factors, such as the characteristics of the patient's anatomy, can also influence the desired relative placement of the multiple ~~implants~~ implements. Some procedures ~~require~~ place the ~~implants to be placed~~ implements at a specified angle relative to each other, while others may ~~require~~ use a parallel arrangement. One such procedure which utilizes a parallel configuration is the fixation of a femoral neck fracture. Typically, this type of fracture is stabilized utilizing three parallel cannulated screws. Each screw is placed perpendicularly to the fracture site and in such a manner that the distance between each screw is equal, thus forming an equilateral triangle. Parallel placement of the screws is ~~important~~ desired so that the bones are properly pulled together. If the screws are not placed in such a parallel manner, shearing forces at the fracture site can prevent proper healing. Furthermore, the triangular screw arrangement increases the stability of the fracture fixation and prevents rotation between the bone

fragments. Studies have suggested that three screws are an optimal number since additional ~~implants~~implements provide no strength advantage and additional screw penetration increases risk. Femoral neck fracture stabilization using this method can be performed percutaneously while the patient is under regional anesthesia, thus reducing risk associated with more invasive procedures.

Prior art

Traditional techniques to accurately position and orient ~~implants~~implements have included the use of x-ray images to localize the position of the ~~implant~~implement tool guide. Through the continuous acquisition of x-ray images during the ~~implant~~medical procedure, real-time placement of the tool guide relative to the patient's anatomy can be displayed. More recently, fluoroscopically-based surgical navigation systems have been employed for tool guide positioning by tracking the tool and superimposing its representation onto pre-acquired images without requiring x-rays to be continually taken during the actual surgical procedure.

Current practice for multiple ~~implant~~implement placement utilizing image-based surgical navigation systems typically employs tracked guides which contain a single cannula. As used herein, the term cannula refers to a tubular member having at least one hollow channel (i.e., lumen), for insertion ~~in~~ and/or placement adjacent to a patient's body. Such an instrument could be used to place ~~tools or implants into~~implements in and/or adjacent to a patient by positioning the cannula in the ~~anatomy region~~anatomy region of interest, and then ~~inserting~~placing the ~~tool or implant into~~implement in the region by means of the channel.

As used herein, the term implement refers to a surgical tool or device for performing medical procedures. An implement could be a drill, a guide wire, or implants such as screws, nails, etc.

Those skilled in the art should recognize that there are many different types of cannulas and many different ways in which cannulas could be used. For example, a cannula could be rigid, semi-rigid, or flexible and could be configured in any number of different forms, such as a catheter, needle, endoscope, ~~implant~~implement inserter, and/or ~~tool inserter~~, etc.

Utilizing a single cannula means the surgeon typically will position each ~~implant~~implement individually. The procedure usually starts by attaching a reference tracking frame to the surgical anatomy. X-ray images are then taken utilizing a fluoroscopic imager which is also tracked by the navigation system. The surgeon then positions the tracked guide for the first ~~implant~~implement with the aid of the navigational system display. Once the tool guide is properly positioned, the cannula is used to place the guide wire and subsequent ~~implant~~implement into the desired anatomical site. The next ~~implant~~implement is then placed relative to the first, and so on. In order for the surgeon to properly place the subsequent ~~implant~~implement relative to the previous, new images ~~must be~~are taken with the previous ~~implant~~implement in place.

One difficulty of the current practice is in achieving relative accuracy of the implant/impliment placement. To achieve the desired relative implant/impliment geometry, the surgeon ~~must estimate~~ estimates each trajectory individually based upon the prior implants/impliments. Thus, the relative accuracy is based ~~solely~~ on the physician's estimate. Furthermore, each implant/impliment may ~~require~~ involve generating a new set of images of the patient's anatomy before the subsequent implant/impliment can be placed, which can increase the time of the procedure and radiation exposure to both the patient and operating room personnel.

SUMMARY OF THE INVENTION

The present invention is directed generally to image guided medical procedures, and, particularly, medical procedures which utilize surgical implants/impliments. More specifically, the present invention is directed to an apparatus and method for the simultaneous/combined positioning of multiple implants/impliments, especially those that may be placed in a specific relative geometry.

~~To achieve these objects and other advantages and in accordance with the purposes of the invention, as~~ As embodied and broadly described herein, certain aspects of the invention ~~is/are~~ directed to a multiple cannula tool guide for use in conjunction with image-guided surgical navigation systems.

In one aspect of the invention, a tool guide, having multiple cannulas, has a reference frame attached which contains a plurality of tracking markers. The markers are sensed by an external detector array which is coupled to a computer. The detector data is processed so that the tool guide can be accurately localized with respect to the external detector. Furthermore, the computer also receives a set of images which are acquired prior to the positioning of the tool guide. These pre-acquired image sets may consist of one or more images, taken from different orientations, of a region of interest of the patient's body. Only a single set of images is required to position the plurality of implants. The pre-acquired images are then calibrated so the positions of the tool guide may be registered with the anatomy as displayed by the images. By combining the tool guide positions and the calibrated pre-acquired image data, the positions of the cannulas can be simultaneously superimposed on the images and displayed on a display device. This composite display can then be used by the surgeon to simultaneously position and orient a plurality of cannulas into the patient to facilitate the placement of a corresponding plurality of implants. In accordance with this aspect of the invention, at least one of the cannula lengths can be adjusted with respect to each other, however, their relative angular orientations are fixed.

In another aspect of the invention, the tool guide has the additional feature of allowing the angles, for at least one of the cannulas, to be adjusted with respect to each other. This variability would allow an apparatus for angular adjustments of the cannula in either the longitudinal and transverse planes along the axis of the tool guide, or a combination of both.

Relative positioning accuracy can be obtained by current implants which are sequentially positioned. The simultaneous positioning lessens the need for the surgeon to estimate relative geometry of implants required during sequential positioning. Furthermore, improvements in efficiency of multiple implant procedures can also be realized through the simultaneous positioning of implants and through the reduction use in image guided surgery is presented. The apparatus comprises: an instrument location system for detecting position, where the instrument location system includes a computer processor; a tool guide comprising a plurality of cannulas; and at least one trackable marker provided on the tool guide for detection by the instrument location system; a memory coupled to the computer processor stores: at least one pre-acquired image of a patient having an image space, and instructions, to be executed by the computer processor, to align the image space to a detector space, to track a three-dimensional position of the tool guide in the detector space, and to compute a projection of the tool guide into the at least one pre-acquired image.

In another aspect of the invention, an apparatus for the placement of surgical implements is presented. The apparatus comprises: a plurality of cannulas coupled to a fixture, where at least one trackable marker associated with the cannulas; a plurality of surgical implement receivers provided on the fixture for receiving surgical implements; and at least one of the plurality of receivers being substantially coaxially aligned with a respective one of the plurality of cannulas.

In another aspect of the invention, an apparatus for the placement of surgical implements, is presented. The apparatus comprises: a plurality of cannulas, where at least one of the plurality of cannulas is adjustable to vary its length; a fixture coupled to the plurality of cannulas, where the fixture can accommodate at least one of the plurality of cannulas being individually adjustable to vary at least one of its angular position; and at least one trackable marker associated with the cannulas.

In another aspect of the invention, a method for guiding a medical instrument for use in image guided surgery is presented. The method comprises: providing at least one pre-acquired image of a patient, the at least one image having an image space; aligning the image space and a detector space; tracking a three-dimensional position of a tool guide in the detector space, using at least one trackable marker provided on the tool guide, where the tool guide includes a plurality of cannulas; and relating the position of the cannulas with the at least one pre-acquired image.

Combined positioning of surgical implements may mitigate the amount of estimation performed by the surgeon during the performs when positioning implements individually. This can result in improved placement efficiency and reduced surgical procedure time. Additional savings in time may also be realized given that only a single set of by reducing the number of pre-acquired images need be acquired prior to the positioning of the implants, whereas the prior art techniques require a separate set of images associated with sequential positioning of each implant. In light of the foregoing, there is a need for an improved device and method for the efficient and accurate

placement of multiple implants generated during a surgical procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

FIG. 1 is a simplified block diagram of a system for the simultaneous combined positioning of multiple surgical implants/implements consistent with the present invention.

FIG. 2 is a simplified side view of an embodiment of a system for the simultaneous combined positioning of multiple surgical implants/implements consistent with the present invention.

FIG. 3 is a perspective view of an embodiment of a tool guide consistent with the present invention.

FIG. 4 is a rear view of the embodiment of the tool guide shown in FIG. 2.

FIG. 4a is a perspective view of another embodiment of a tool guide consistent with the present invention.

FIG. 4b is another embodiment of the tool guide having the ability to adjust the relative angle/angles between the cannulas.

FIG. 5 is a block diagram of a process used to place surgical implants/implements consistent with the present invention.

FIG. 6 is a simplified block diagram of an exemplary computer system used in the surgical navigation system in accordance with one embodiment of the invention.

FIG. 7 is an exemplary diagram of a display consistent with an embodiment of the invention showing the trajectory of cannulas superimposed on images of a patient's anatomy.

DETAILED DESCRIPTION

Reference will now be made in detail to the present preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

With reference to FIG. 1, there is shown schematically an apparatus in accordance with the present invention for the simultaneous combined positioning of multiple surgical

~~implants/implements.~~ Image-based surgical navigation system 100 enables a surgeon to generate and display on monitor 115 a plurality of positions representing each cannula 127 of tool guide 125. Data representing one or more pre-acquired images 105 is fed to navigation computer 110. The pre-acquired images, generated prior to ~~implant/implement~~ placement, typically are taken from different orientations and represent the region of interest of a patient's body which is to receive the ~~implants/implements~~. Navigation computer 110 tracks the position of tool guide 125 in real time utilizing a detector. The detector may be an sensor array 120 physically uncoupled from tool guide 125. Alternatively, the detector could also be at least one trackable marker 121 physically attached to or integrated into tool guide 125. Computer 110 then registers and displays the position of each cannula 127 with images 105 in real time to allow the surgeon to properly position and orient the tool guide into the anatomy for ~~implant/implement~~ placement. The pre-acquired images 105 are superimposed on the icons representing each cannula 127 on monitor 115. While the present invention described in more detail below is exemplified by a fluoroscopic-based system used for femoral neck fracture fixation, it is not limited to the described embodiment.

FIG. 2 illustrates apparatus 125 in use with a preferred image-based surgical navigation system 200 according to one embodiment of the present invention. System 200, described below in sufficient detail to allow an understanding and appreciation of the present invention, is explained in greater detail in U.S. patent application Ser. No. 09/274,972 of David A. Simon et al., entitled "Navigation Guidance via Computer Assisted Fluoroscopic Imaging," filed on Mar. 23, 1999, now U.S. Pat. No. 6,470,207, issued Oct. 22, 2002, the entire disclosure of which is hereby incorporated by reference. However, it must be understood that the invention is not confined to use with this particular image guided surgical system.

Further referring to FIG. 2, an image-based surgical navigation system 200 for acquiring and displaying x-ray images appropriate for a given surgical ~~implant/implement~~ procedure is shown. Pre-acquired images of patient 202 are collected when a patient, lying on platform 205, is placed within C-arm 212 of imaging device 210. The term "pre-acquired," as used herein, does not imply any specified time sequence. Pre-acquired images could be generated pre-procedurally or intra-procedurally. ~~The only requirement is that~~ Preferably, the images be taken before ~~implant/implement~~ positioning is performed.

C-arm 212 may be capable of rotating relative to patient 202, allowing images of the patient to be taken from multiple directions. For example, the surgeon may rotate C-arm 212 about its mechanical axis as shown by arrows 228. Usually, images are taken from two substantially orthogonal directions, such as anterior-posterior (A-P) and lateral, of the anatomy which is to receive the surgical implants. Imaging system 210 further includes x-ray source 214 and x-ray receiving section 216 mounted on opposite sides of C-arm 212, and a calibration and tracking target 218. ~~Calibration and tracking target 218 includes sensors 220, target tracking markers 222, and calibration markers 224. System 210 further includes C-arm control computer 226 which allows a physician to control the operation of imaging device 210, such as setting imaging and positioning~~

~~parameters. implements.~~ One implementation of imaging device 210 is the Model 9600 C-arm fluoroscope from OEC Medical Systems, Inc. of Salt Lake City, Utah, ~~although calibration and tracking target 218 is typically not included in the Model 9600 C-arm fluoroscope and may have to be added, however, the 9600 is otherwise structurally similar to imaging device 210.~~

It is to be understood, however, that the invention is not confined to the use of ~~this type of imaging device.~~

~~In operation, x-ray source 214 generates x-rays that propagate through the patient 202 and calibration markers 224 and into x-ray receiving section 216. Receiving section 216 generates an image representing the intensities of the received x-rays. Typically, receiving section 216 comprises an image intensifier that converts the x-rays to visible light and a charge coupled device video camera that converts the visible light image to a digital image. Receiving section 216 may also be a device that converts x-rays directly to digital images, thus potentially avoiding distortion introduced by the first conversion to visible light.~~

a C-arm fluoroscopic device. Other embodiments of the invention could include imaging systems which produce 3-D volumetric data. Examples of such 3-D imaging systems include computer tomography, ultrasound, or magnetic resonance imaging. Functional imaging systems such as, for example, functional magnetic resonance imaging, positron emission tomography, single photon emission tomography, or magnetoencephalography, could also be used.

Fluoroscopic images taken by imaging system 210 are transmitted to computer 226 where they may be forwarded to surgical navigation computer 110. Image transfer may be performed over a standard video connection or a digital link. Computer 110 provides the ability to display, via monitor 115, as well as save, digitally manipulate, or print a hard copy of the received images. Images, instead of, or in addition to, being displayed on monitor ~~124~~115, may also be displayed to the surgeon through a heads-up display or some other type of appropriate display device.

Although computers 226 and 110 are shown as two separate computers, they alternatively could be variously implemented as a single-chassis multi-processor computer or as a single computer that performs the functions performed by individual computers 110 and 226. In the single computer case, such computer would directly receive image data from image device 210 directly and detector 120.

~~Sensors 220 sense the presence of radiation, which is used to determine whether or not imaging device 210 is actively imaging. The results of such detection is relayed to navigation computer 110. Alternatively, a person may manually indicate when device 210 is actively imaging, or this function can be built into x-ray source 214, x-ray receiving section 216, or control computer 226.~~

~~In operation, patient 202 is positioned between the x-ray source 214 and the x-ray~~

receiving section 216. In response to an operator's input command to control computer 226, x rays emanate from source 214, pass through patient 202, calibration markers 224, and into receiving section 216, which generates a two dimensional image of the patient. C-arm 212 is capable of rotating relative to patient 202, allowing images of the patient to be taken from multiple directions. For example, the surgeon may rotate C-arm 212 about its mechanical axis as shown by arrows 228. This movement corresponds to a rotation about the long axis of a patient.

Raw images generated by any x ray receiving equipment, such as receiving section 216 tend to suffer from unavoidable distortion caused by a number of sources. For example, such sources include the inherent characteristics of the image intensifier, external electromagnetic fields, variations in the C-arm's position relative to the Earth's magnetic field, and mechanical non-rigidity in the C-arm's structure. Accordingly, it is desirable that every acquired image be independently calibrated. During the calibration process, computer 110 develops a transform for the fluoroscopic image formation process. This transform geometrically relates how spatial positions, relative to patient 202, project into the fluoroscopic image and conversely, how a given pixel, which has an intensity dependent upon the density of the imaged object, projects back through the patient to the fluoroscope radiation source 214. This geometric transform may be different for every acquired image, therefore calibration must be performed each time an image is taken.

[0034] The development of the geometric transform described above involves placing calibration markers in the path of the x rays, where a calibration marker is an object which is opaque or semi-opaque to x rays. Calibration markers 224 are rigidly arranged in predetermined patterns in one or more planes in the path of the x rays and are visible on the recorded images. Detectable target tracking markers 222 are fixed in a rigid and known position relative to calibration markers 224. Because the true relative position of the calibration markers 224 in the recorded images are known, computer 110 is able to calculate an amount of distortion at each pixel in the image. Accordingly, computer 110 can digitally compensate for the distortion in the image and generate corrected or improved images. A more detailed explanation of methods for performing calibration is described in the following references: B. Schuele et al., "Correction of Image Intensifier Distortion for Three Dimensional Reconstruction," presented at SPIE Medical Imaging 1995, San Diego, Calif., and G. Champeboux et al., "Accurate Calibration of Cameras and Range Imaging Sensors: the NPBS Method," Proceedings of the 1992 IEEE International Conference on Robotics and Automation, Nice, France, May 1992, and U.S. patent application Ser. No. 09/106,109 of D. Simon et al., entitled "System and Methods for the Reduction and Elimination of Image Artifacts in the Calibration of X-ray Imagers," filed on Jun. 29, 1998, the entire contents of all of which are hereby incorporated by reference. Calibration and tracking target 218 serves two functions. The first, as described above, is containing the calibration markers in a fixed position for use in image calibration. The second function, which is described in more detail below, is containing the tracking markers which are sensed by detector 120 for determining the position of receiver section 216.

Further referring to FIG. 2, image-based surgical navigation system 100 generally

performs the real-time tracking of tool guide 125, and, in the ~~preferred~~ shown embodiment, also tracks the position of C-arm receiver section 216 and anatomical reference frame 260. ~~Detector 120 contains~~ This embodiment utilizes a detector which includes a sensor array 240-120 which is suspended by mount 250. ~~Detector 120 is~~ Sensor array 120 may be located in such a manner as to provide sensor array 240 with a clear line of sight to the tracking markers on each tracked object (such as tracking markers 265, described more fully below). ~~Detector~~ Sensor array 120 is coupled to computer 110 which ~~is~~ may be programmed with software modules that analyze the signals transmitted by sensor array ~~240~~ 120 to determine the position of each object in detector space. The manner in which the ~~detector~~ sensor array localizes the object is known in the art, ~~and is discussed.~~ See also, for example, ~~in~~ PCT Application No. PCT/US95/12894 (Publication No. WO 96/11624) to Bucholz, the entire disclosure of which is incorporated by reference.

The tracking markers for each tracked object may be, for example, reflective markers and/or light emitting diodes (LEDs). Other devices known in the art may be used that are capable of being tracked by a corresponding ~~sensor array detector~~ within the scope of the invention. For purposes of illustration, and not by limitation, the tracking means may be acoustic, magnetic, optical, electromagnetic, inertial, and radiological devices known in the art. It should also be understood that different tracking markers for each tracked object can be used.

Not all of the tracking devices listed above are used in conjunction with sensor array 120. For example, a single electromagnetic tracking marker is actually a sensor which may be used to provide at least three degrees of spatial information in detector space. Some electromagnetic sensors can also provide additional attitude information, thus providing up to six degrees of positional information. Such sensors may also have no line of sight constraint which provides the advantage of functioning while embedded within a patient. The manner in which electromagnetic sensors localize an object is well known in the art. See also, for example, PCT Application No. PCT/GB93/01736 (Publication No. WO 94/04938) to Bladen, the entire disclosure of which is incorporated by reference.

In the ~~preferred~~ embodiment of FIG. 2, anatomical reference frame 260, which incorporates a plurality of tracking markers 265, is attached to patient 202 during an ~~implant~~ implement procedure. The reference frame may be securely attached to the anatomy in the region of the body which is to receive the ~~implants~~ implements. Reference frame 260 ~~must~~ may be placed in a position so that the markers are visible to ~~detector~~ sensor array 120 during the image acquisition process and the ~~implant~~ implement procedure. By sensing attached tracking markers 265, computer 110 can determine the position of the anatomy in detector space. This information is later used by computer 110 to register pixels found in the images to the position of the patient's anatomy as described in detector space. For purposes of this document, detector space is defined herein as the three-dimensional reference coordinate system associated with the detector-120. ~~As previously discussed, calibration and tracking target 218 also contains a plurality of target tracking markers 222 for localization of receiver section 216 in detector space. This~~

information is also required by computer 110 to register the image pixels with the patient's anatomy.

In general,

Further referring to FIG. 2, multiple cannula tool guide 125 ~~is~~ may be tracked by surgical navigation system 100 using attached tracking markers 230 in order for its position to be determined in detector space. Computer 110 integrates this information with the pre-acquired images of patient 202 to produce a display which assists surgeon 270 when performing multiple ~~implant~~implement procedures. Representations of multiple cannulas 127 are ~~simultaneously~~ overlaid on the pre-acquired images of patient 202 and displayed on monitor 115. In this manner, surgeon 270 is able to see the location of the cannulas relative to the patient's anatomy, and can ~~simultaneously~~ position and orient multiple ~~implants~~implements into the desired portion of patient's body.

Image-based surgical navigation system 100 utilized in the ~~preferred~~ embodiment of the ~~present invention~~ shown in FIG. 2 may be the same as that used in the FluoroNav.TM. system, which utilizes the StealthStation.RTM. Treatment Guidance Platform, both of which are available from Medtronic Sofamor Danek, Inc.

FIG. 3 is a perspective drawing of an embodiment of tool guide 125 which is optimized for the ~~simultaneous~~combined positioning of cannulated screws to secure femoral neck fractures. A plurality of tracking markers 230 are positioned at ~~discrete points along the periphery~~ on the upper surface of frame 300. Frame 300 firmly attaches to ~~the~~ body 305 of ~~the~~ tool guide 125 by sliding onto a dovetail formed on the top of mounting post 380. Frame 300 may be interchanged with other frames which utilize different sizes or shapes, or tracking markers of a different type. In the ~~preferred~~ embodiment shown in FIG. 3, tracking markers 230 ~~are~~ may be infrared LEDs and/or reflective markers such as those supplied by Northern Digital Inc. ~~This embodiment of the guide contains three~~

For the embodiment shown in FIG. 3, tool guide 125 includes three substantially parallel cannulas 310a, 310b, 310c. Cannula 310a has a fixed length, ~~while~~ and the other cannulas 310b, 310c have lengths which are variable. ~~The~~ However, in general, the invention could comprise a tool guide where all the cannulas, or any subset thereof, may have variable lengths of. The variable length cannulas can be independently adjusted by the use of threaded means 330, which screw into interchangeable fixture 350 and are locked in place using a set screw or jam nut (not shown). Variable length cannulas allow tool guide 125 to adapt to the varying surface shapes associated with different bone structures. ~~These~~ The surgeon, using information from the pre-acquired images, can make the proper length adjustment to each adjustable cannula during the pre-operative planning stage of the medical procedure. The cannulas may possess teeth 360a, 360b, 360c at their distal end in order to effectively grip the patient's bone. ~~The surgeon holds and manipulates guide 125 by grasping handle 340.~~

Furthermore, tool guide 125 may have cannulas which have inner and outer diameters that are also variable. These diameters may be altered by simply interchanging a given

cannula with another having differing diameters, or alternatively, using cylindrical adapters to modify the diameters of an existing cannula. For example, the inner diameter of the lumen may be reduced by inserting a reduction sleeve which extends the length of the cannula. Various reductions in lumen diameter can be achieved through the insertion of one or more reduction sleeves. Alternatively, the outer diameter of a cannula may be increased in a similar manner by sliding one or more expansion sleeves over the outside of the cannula. Other embodiments of tool guides containing can be provided by changing fixture 350. For example, one such interchangeable fixture 350 could have cannulas with non-parallel, fixed angular offsets between. In the cannulas can easily be realized by changing fixture 350. In this embodiment of FIG. 3, cannulas 310b and 310c can be removed by unscrewing them from fixture 350. The fixture may then be slid off cannula 310a and replaced with another having different characteristics. For example, the number of cannulas can be varied by utilizing fixtures which have a different number of attachment points. Additionally, the relative geometry, or spread, between the cannulas can be varied by utilizing fixtures which have attachment points in different relative locations. Finally, the relative angulations among the cannulas may be altered from a parallel configuration by employing a fixture having attachment points with fixed angular offsets.

Many different types of cannulas could be used with the invention in its broadest aspects. In the preferred embodiment shown in FIG. 3, the cannulas 360a, 360b, 360c are preferably substantially rigid tubular members each having a lumen extending therethrough that is configured to allow for passage of ~~tool~~ surgical implements, such as drills or other tools, and/or devices, such as cannulated screws, nails, etc.

The surgeon typically holds and manipulates tool guide 125 by grasping handle 340 shown in FIG. 3. Alternatively, the invention could also be physically manipulated by a machine, such as, for example, a robotic arm. Machine manipulation could be facilitated through a coupling on body 305 which could allow tool guide 125 to be removably attached to a mechanized placement system. This arrangement could facilitate highly accurate placement of surgical implements, without usage of handle 340.

FIG. 4 is a rear-view perspective drawing of the embodiment of the tool guide 125 shown in FIG. 3. Situated at towards the proximal end of the each cannula is a flange 370, and attached to body 305. At the flange center is a countersunk hole 375 which leads to the duet lumen of the cannula. This arrangement is to aid Flange 370 and hole 375 is a surgical implement receiver which assists the surgeon in the placement of tools and implantsimpliments down the cannulas once the tool guide 125 is properly positioned in the patientspatient's body. For a procedure, for example, to secure a femoral neck fracture, a drill with an attached guide wire is sequentially placed down each cannula after tool guide 125 has been appropriately positioned relative to the patient's body. The surgeon drills into the bone in order to anchor the guide wire. A cannulated screw is then placed over each guide wire which tapsand the screw is tapped into the bone at the fracture site. Once the screws are in place and secured, the guide wires are removed along with the tool guide.

FIG. 4a shows an embodiment of a tool guide having electromagnetic sensors attached to cannulas 310a, 310b, and 310c. Electromagnetic sensors may be placed at the approximate mid-point of each cannula, as shown by 315a, 315b, and 315c, and/or they may be placed towards the tips of each cannula as shown by 317a, 317b, and 317c. Electromagnetic sensor groups 315a-c and 317a-c may be used separately or in conjunction with each other. Utilizing both groups can allow for the extraction of trajectory information of each cannula. Typically, each cannula would be equipped with separate electromagnetic sensors, however; some embodiments may have just one, or any subset of the total number of cannulas, equipped with electromagnetic sensors.

FIG. 4b exemplifies another embodiment of a tool guide having cannulas with adjustable relative angles. Cannulas 401 and 402 are set in fixture 405 such that the base of each cannula can pivot within the fixture. The angle of each cannula can be varied independently in the azimuth, θ , 412 and elevation, ϕ , 414 directions relative to fixture 405. After the angles for each cannula have been adjusted as desired, mechanism 410 can lock each cannula in place. Mechanism 410 can be a friction or compression lock, or any other type of locking mechanism known in the art. The orientation of cannulas 401, 402 shown as mutually parallel in FIG. 4a4b is only for purposes of explanation, and not limitation. Other embodiments which allow the cannulas to vary in angle have a varying angular position which are known in the art could be used. It should also be understood that the tool guide shown in FIG. 4a4b could have any number of cannulas, and in addition to each angle being variable, each cannula could be individually adjusted in length.

FIG. 5 is a flowchart illustrating methods for simultaneous-multiple implant implement positioning using image-based surgical navigation techniques. The surgeon begins may begin by acquiring one or more images of a patient. In the preferred one embodiment, these are may be acquired with fluoroscopic x-ray imager 210, as shown in system of FIG. 2. Alternatively, such images may be acquired with an imaging device with provides 3-D volumetric data (step 510). As previously described, acquiring an x-ray image actuates sensors 220, which informs computer 110 of the beginning and end of the radiation cycle used to generate the images. The fluoroscopic imager 210 must be stationary with respect to the patient 202 to provide an image of sufficient quality for use in navigational system 100. If C-arm 212 or patient 202 is moving during image acquisition, the position of the fluoroscope will not be accurately determined relative to anatomical reference frame 260. Thus, it is important that the recorded position of imager 210 reflect the true position of the imager at the time of image acquisition. If imager 210 moves during the image acquisition process, or if imager 210 moves after image acquisition but before its position is recorded, the calibration process will produce poor results. To prevent this type of error

Computer 110 then retrieves a pre-acquired image and correlates the spatial coordinates defined by the images, known as image space, with the spatial coordinates defined by the detector, known as detector space. As shown in the embodiment of FIG. 2, computer 110

may examine the position data from the target tracking markers 222 as sensed by detector 120 while sensors 220 are signaling radiation detection. If the calibration and tracking target 218 moves relative to the anatomical reference frame 260 during imaging, the image is marked as erroneous (step 510).

At the end of the radiation cycle, computer 110 retrieves the ~~retrieve~~ a pre-acquired image from C-arm control computer 226 and ~~retrieves~~. Computer 110 then determines location information of the target tracking markers 222 receiver section 216, and anatomical reference frame markers 265 from detector 120, using sensor array 120. Computer 110 calibrates the acquired image by correcting distortions which may be present and then correlates the ~~image~~ images to anatomical reference marker 260, by determining and applying the ~~a~~ geometric transform as described previously, well known to those skilled in the art. Computer 110 then stores the image along with its positional information (step 520). The processes described in step 520 are repeated for each image to be acquired.

~~The implant~~ The implement placement procedure starts once a detector 120 and computer 110 detect and track the position of the tool guide 125 relative to ~~anatomical reference frame 260, and hence relative to patient 202 in detector space~~. With this information, computer 110 dynamically calculates, in real time, the projections of cannulas 127 into each fluoroscope image as tool guide 125 is moved by surgeon 270. ~~In the preferred embodiment~~ Typically, the surgeon places the cannulas into the patient percutaneously into the region of interest to position the ~~implants~~ implements (step 530). However, the invention can be used with other surgical techniques.

Graphical representations of cannulas are superimposed on pre-acquired images and displayed on monitor 115. The cannulas can be displayed, simultaneously if desired, and in real time relative to the patient's anatomy (step 540). The surgeon, utilizing the display, can then manipulate tool guide 125 and position cannulas 127 in the region of interest. Using real-time display 115, the physician gets feedback on how the cannulas are oriented relative to the anatomy and then determines the optimal orientation (step 550). Once this is determined, the surgeon will then sequentially place the ~~implants~~ implements into the patient. If, for example, the procedure involves the fixation of a femoral neck fracture as previously described, the surgeon first places a drill with an attached guide wire down the cannula to drill into the bone at the fracture site and then anchor the guide wire into the bone. The surgeon then places a cannulated screw over the guide wire and down into the cannula. The screw taps into the bone at the fracture site and pulls the separate pieces of bone together. This process is repeated for each ~~implant~~ cannulated screw while the surgeon steadily holds tool guide 125 in place. Alternatively, the surgeon may place the guide wires using the cannulas and then remove the guide from patient's body. The surgeon would then position the screws by placing them over each guide wire, leading them to the bone into the fracture site (step 560).

Referring to FIG. 6, components and modules of a computer system 110 used to perform various processes of the present invention are described. Although a STEALTH STATIONS.RTM. image guided system manufactured by Medtronic Sofamor Danek has

been identified, it will be appreciated that the present invention may be utilized with other types of computer systems. One aspect of the computer system 110 includes a graphical user interface system operating in conjunction with a display screen of a display monitor 115. The graphical user interface system is preferably implemented in conjunction with operating system 615 running computer 110 for displaying and managing the display objects of the system. The graphical user interface is implemented as part of the computer system 110 to receive input data and commands from a conventional keyboard 620 and mouse 625. For simplicity of the drawings and explanation, many components of a conventional computer system have not been illustrated such as address buffers, memory buffers, and other standard control circuits because these elements are well known in the art and a detailed description thereof is not necessary for understanding the present invention. A computer program used to implement the various steps of the present invention is generally located in memory unit 600, and the processes of the present invention are carried out through the use of a central processing unit (CPU) 605. Those skilled in the art will appreciate that the memory unit 600 is representative of both read-only memory and random access memory. The memory unit also ~~contains~~includes a database 650 that stores data, for example, image data and tables, including such information as position data and geometric transform parameters, used in conjunction with the present invention. CPU 605, in combination with the computer software comprising operating system 615, ~~seanning~~detection software module 630, tracking software module 635, calibration software module 640, and display software module 645, controls the operations and processes of computer system 110. The processes implemented by CPU 605 may be communicated as electrical signals along bus 660 to an I/O interface 670 and a video interface 675.

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Detection software module 630 utilizes signals from the detector and performs the processes associated with creating a coordinate reference system and detecting positions of reference images for use in connection with the present invention and are known to those skilled in the art. Tracking software module 635 performs the processes necessary for tracking objects in an image guided system as described herein and are known to those skilled in the art. ~~Calibration~~Correlation software module 640 computes the geometric transform which ~~corrects for image distortions and registers the images to the anatomical reference frame 260~~detector space, and thus the patient's anatomy.

Display software module 645 applies, and if necessary, computes the offsets between ~~the tool~~ guide tracking markers 230 and the cannulas in order generate an icon representing each cannula for superposition over the images. For tool guides with fixed cannulas, these offsets can be measured once and stored in database 650. The user would then select from a list of tool guides which one was being used in the procedure so the proper offsets are applied by display software module 645. For tool guides with variable lengths and angulations, the offsets could be measured manually and entered via keyboard 620, or measured using the navigation system 100 in conjunction a tracked pointer or tracked registration jig (not shown). If a tracked pointer is used, the user will touch the tip and tail of each cannula while the tool guide is being tracked. The offsets are

computed by display software module 645 and stored for later use. Similarly, if a tracked registration jig is used, the tool guide is placed within the jig while it is being tracked. The jig will measure the positions of the cannulas and display software module 645 will again compute the offsets and store them for later use in database 650.

Pre-acquired image data 105 can be fed directly into computer 110 digitally through I/O interface 670, or may be supplied as video data through video interface 675. In addition, items shown as stored in memory can also be stored, at least partially, on hard disk 680 if memory resources are limited. Furthermore, while not explicitly shown, image data may also be supplied over a network, through a mass storage device such as a hard drive, optical disks, tape drives, or any other type of data transfer and storage devices which are known in the art.

FIG. 7 shows an exemplary diagram of display 700 illustrating ~~the~~ an iconic graphical overlay of the cannulas for the preferred embodiment. Display 700 is presented to the surgeon on monitor 115 of computer system 110. The left side of FIG. 7 shows a fluoroscopic image of an anterior-posterior view of a hip and femoral neck bone 710. Graphical overlays 715 are the iconic superposition of all the cannulas 127 attached to tool guide 125 within image 710. Graphical overlays 715 are directional indicators, displaying the position and orientation of each cannula. In the embodiment shown in FIG. 7, these directional indicators are shown as lines, but other symbols may be used. As the surgeon moves the tool guide 125, computer 110 recalculates and displays the new locations of the graphical overlays 715. The surgeon can use image 710 and overlays 715 to visualize, in real-time, the position and orientation of the cannulas relative to the patient's anatomy.

Typically

For the embodiment shown in FIG. 2, the surgeon would like to acquire two substantially orthogonal fluoroscopic images of patient 202, such as images from an anterior-posterior view and a lateral view of the anatomy of interest. These two complementary views help the surgeon to better visualize how the cannulas are situated in the patient's anatomy. The orthogonal views are related to one another by a 90 degree rotation about the major axis of the patient (the axis running along the length of the patients body). The fluoroscopic image taken from the lateral view 720 is shown on the right side of FIG. 7, along with graphical overlays 717 showing the locations of the cannulas 127.

In certain situations, the surgeon may wish to know where the tip of the cannulas would be if cannulas were projected along a line give by ~~the~~ a tool guide's current trajectory. At the surgeon's command, computer 110 may calculate and display this projection based upon the current orientation and position of the cannulas. This orientation and position are determined by tracking the tip and the tail of each cannula. The estimated position of the tip can be calculated by computer 110 through projecting a fixed distance beyond the cannulas' tips in the direction of the line formed by each cannula's tip and tail. The estimated position, or "look-ahead" trajectory, would be represented by a graphical overlay. As shown, an in FIG. 7, exemplary "look-ahead" trajectorytrajectories 725 and

727 ~~is~~are shown in a different line ~~style~~styles from overlay 715 and 717, respectively. This difference could also be a change in color, type, or texture between the look-ahead trajectory 725, 727 and the current position 715, 717. Computer 110 may vary the length of the look-ahead trajectory 725, 727 as directed by the surgeon through the graphical user interface control 730 and computer keyboard 620 or mouse 625. In this manner, computer 110 assists the surgeon in visualizing where the cannulas would be in the patient if they were advanced a predetermined distance into the body of the patient.

Although the look-ahead technique described above projected the graphical representation of the cannulas into the image, there is no requirement that the cannulas' graphical representation be in the space of the image for look ahead trajectory 725, 727 to be projected into the image. In other words, for example, the surgeon may be holding tool guide 125 above the patient and outside the space of the image, so that the representation of the cannulas does not appear in the images. However, it may still be desirable to project ahead portion 725, 727 into the image to facilitate planning of the ~~implant~~implement procedure.

The look-ahead technique could be extended to include virtual implants. Graphical overlays representing implant structures such as prosthetic devices, plates, and fasteners such as screws, nails, etc., could be shown on display 115 during and after their placement into the patient's body. These graphical overlays would provide additional information regarding the implants without involving the generation of new images.

When cannulas 127 are perpendicular to the plane of the fluoroscopic image, the graphical overlay of the cannulas ~~essentially collapses~~may virtually collapse to a point, potentially making it difficult to view them. To alleviate ~~the problem~~this, computer 110 may optionally use a different graphical representation of cannulas 172 when the distance in the image plane between the tip and tail of the cannulas 127 becomes smaller than some fixed distance.

The foregoing description is presented for purposes of illustration and explanation. It is not intended to be exhaustive or to limit the invention to the precise form disclosed, and modifications or variations are possible in light of the above teachings or may be acquired from practice of the invention. The principles of the invention and its practical application enable one skilled in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated.

For example, pre-acquired images obtained from ~~different modalities~~ may be used in place of those produced by different than the C-arm fluoroscope x-ray imager may be used with the invention. Such modalities could supply 3-D volumetric data and may also include functional information. Such modalities may include, by way of example only, computer tomography, ultrasound, or magnetic resonance imaging. Imaging modalities which may provide functional information include functional magnetic resonance imaging, positron emission tomography, single photon emission tomography,

magnetoencephalography, or any other modality known to those skilled in the art.

Furthermore, the invention is not limited to the fixture of femoral neck fractures, but can be used for many different types of procedures such as the distal locking of intramedullary nails, ~~planting implants into the spine~~in placing implements such as interbody fusion devices into the spine, anterior cervical plating systems, etc., or any other application where two or more ~~implants have~~implements are to be placed, especially multiple implements having fixed relative positions and angulations.

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